Exploration Medical Capability

Algorithm-based Fluid Resuscitation

Human Research Program
Technology Development Plan – Rev A

(21 May 2015 version)

Submitted by:

Lauren Sharp/NASA GRC

John McQuillen/NASA GRC

Sam Hussey/NASA GRC

Table of Contents

1. Objectives of Algorithm-based Fluid Resuscitation

The current gap under Exploration Medical Capability (ExMC) 4.12 states that the capability to generate and utilize sterile intravenous fluid from potable water during exploration missions does not exist. The risks associated with this gap are unacceptable health and mission outcomes due to limitations of in-flight medical capabilities. This Technology Development Plan (TDP) outlines a plan for the development of algorithm-based fluid resuscitation to utilize and administer sterile intravenous fluid to an ill crew member on an exploration mission.

Hours of medical training are required before health care providers have the required skill to conduct fluid resuscitation. This task will develop an intelligent system for fluid resuscitation to reduce the medical training required. Algorithm-based fluid resuscitation will utilize automation and feedback control to administer IV fluid to an ill crew member during an exploration mission. This is an effort to mitigate the risks and close ExMC 4.12 in direct support of Exploration class missions to the Moon, Mars, or other solar system destinations.

2. Technical Approach

Work in this gap area will begin with identification of conditions requiring IV fluid delivery based on the Exploration Medical Condition List (EMCL). The operational concept and requirements for the IV fluid delivery system or systems will then be defined and documented. A market survey and literature search will be performed on any existing technologies relating to fluid resuscitation. Subsequently, technologies for an algorithm-based fluid resuscitation system will be selected for further development. Following delivery of the prototype system, further development will proceed according to the NASA hardware development cycle. Work will continue with the demonstration of the algorithm-based fluid resuscitation system in a ground-based environment.

To develop a TRL 6 algorithm-based fluid resuscitation system, the technical approach will include the following steps, as described above:

1. Determine which conditions require IV fluids
2. Define the operational concept for the algorithm-based fluid resuscitation system
3. Document the requirements for the algorithm-based fluid resuscitation system
4. Perform a market survey and literature search for algorithm-based fluid resuscitation systems
5. Develop the algorithm-based fluid resuscitation system
6. Evaluate the effectiveness of the algorithm-based fluid resuscitation system in a ground-based environment [TRL 6]
7. Produce the final report on the algorithm-based fluid resuscitation system. Assess for impacts to the research plan.

2.1 Problem Statement

Currently on the International Space Station (ISS), an ill crew member can be returned to Earth for definitive care in a timely manner. For exploration missions, however, timely evacuation to Earth will not be possible. Therefore, the ability to administer IV fluid to

an ill crew member is desired to address the medical conditions of concern. Development of clinical algorithms to tailor IV fluid delivery (rate and volume) to a crew member's medical condition will be pursued under this gap.

2.2 Candidate Technologies

Several candidate technologies have been identified from information given during interviews with clinical and technical experts as in addition to documented literature. One candidate technology is TBD.

2.3 Trade Study Results

These are the results from the trade study performed for this task.

2.4 System Concept

An algorithm-based fluid resuscitation system for Exploration missions is envisioned to consist of three units or modules: (1) to monitor an ill crew member's vitals, (2) to decide on the volume of IV fluid the crew member requires based on his/her medical condition, and (3) to deliver the desired volume of IV fluid at the appropriate rate of delivery. The concept is illustrated in Figure TBD.

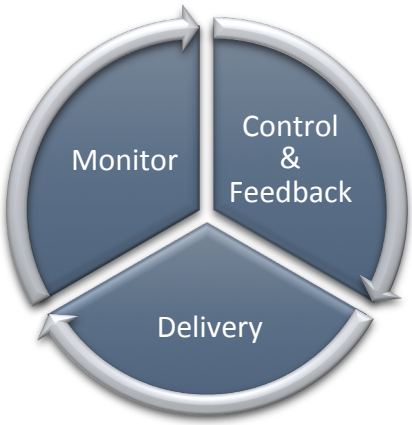

Figure TBD. A conceptual illustration of the process.

2.4.1 Monitoring Unit

The Monitoring Unit will serve as a database to save, store, playback, and transmit data to the Control and Feedback Unit and, if necessary, transmit data to a ground-based practitioner. The Monitoring Unit shall have the capability to record data automatically from vital measurements and manually from observations by a crew member serving as the health care provider. Examples of data automatically recorded and stored by the Monitoring Unit include heart rate, blood pressure, temperature, respiration rate, and oxygen saturations. Manual inputs include observations of blood loss, urine volume output, signs of dehydration (dry mouth, dry skin), level of consciousness, nausea and dizziness. This data needs to be saved and stored, at least temporarily, aboard exploration vehicles or outposts. The Monitoring Unit will need to be able to send this data to the Control and Feedback Unit. In addition, the capability to downlink this data to ground stations is needed for further medical evaluation, if necessary.

2.4.2 Control & Feedback Unit

The Control & Feedback Unit receives data from the Monitoring Unit and makes decisions based on the ill crew member's condition to adjust the IV fluid output accordingly. The medical data received from the Monitoring Unit is scored according to a predetermined score sheet. An example of a score sheet is shown in Figure TBD.

PHYSIOLOGICAL PARAMETERS	3	2	1	0	1	2	3
Respiration Rate	≤8		9 - 11	12 - 20		21 - 24	≥25
Oxygen Saturations	≤91	92 - 93	94 - 95	≥96			
Any Supplemental Oxygen		Yes		No			
Temperature	≤35.0		35.1 - 36.0	36.1 - 38.0	38.1 - 39.0	≥39.1	
Systolic BP	≤90	91 - 100	101 - 110	111 - 219			≥220
Heart Rate	≤40		41 - 50	51 - 90	91 - 110	111 - 130	≥131
Level of Consciousness				A			V, P, or U

Figure TBD. NEWS: National Early Warning Score, developed by the Royal College of Physicians 2012.

2.4.3 Delivery Unit

The Delivery Unit takes the output from the Control and Feedback Unit and delivers the recommended volume of IV fluid to the ill crew member at the appropriate rate of delivery. The Delivery Unit

2.5 Justification for Directed Study

Fluid resuscitation is one of the most important and difficult issues in the critically ill patient. Therefore, the volume status of each and every ICU patient needs to be assessed on an ongoing basis (Merik, 2010). The human body needs water for proper organ functioning. The consequences of dehydration include, and even death. Without the capability for algorithm-based fluid resuscitation, thus produces the risk of unacceptable health and mission outcomes exists.

3. Performance

Key performance parameters relating to the operation of the algorithm-based fluid resuscitation system include:

Monitor the ill crew member's vitals,
Control the volume of IV fluid to be administered and the rate of delivery,

Deliver IV fluid to the ill crew member,
Provide feedback to the Control Unit

4. Management Approach

4.1 Management Structure

Technology for the Algorithm-based Fluid Resuscitation system will be managed by the Glenn Research Center. The TD technical lead will be TBD, with TBD as the task manager. The Exploration Medical Capabilities (ExMC) Element of the Human Research Program has overall management responsibility for this task.

Personnel at the Glenn Research Center, unless otherwise noted, will accomplish all tasks in the Work Breakdown Structure (WBS). The WBS and schedule identifies tasks along with appropriate deliverables and milestones included in the overall effort. Within the Glenn Research Center, management authority resides within the ISS and Human Research Office of the Space Flight Systems Directorate. Technical work is accomplished by personnel within Glenn's TBD Branch which is part of the Research Directorate at the Glenn Research Center.

Because NASA governing documents require all centers to operate as matrix organizations with line managers responsible to assign personnel, individuals performing specific tasks may change through the life of the development. Both project and supervisory management, however, will ensure that key skills required to successfully complete the task are available.

4.2 Problem Reporting and Controls

The task will operate under the philosophy that problems that do not affect visibility and controlled milestones, budgets, or deliverables will be dealt with internally, either at the task or element level. Problems that do affect visibility and controlled milestones, budgets, or deliverables shall be elevated to the appropriate control board for review, corrective action approval, disposition, and recording.

Accordingly, task personnel will execute this task as described within this plan. Any problems within the task will be first reported to the GRC technology development lead and task manager to be resolved within the team. If the team's corrective action does not prevent negative impacts to content, schedule, or budget, the problem will be elevated to the element level, at which point the element manager will either resolve the problem within the element, or if that cannot be done, develop the appropriate corrective action and propose that action to the appropriate control board.

4.3 Management Tools

The task shall report progress to the Exploration Medical Capability Manager at intervals determined by the manager.

4.4 Task Priorities and Records Management

All records generated by the task shall be retained in electronic format and stored in the eRoom tool provided by GRC. The GRC ExMC lead shall be responsible for ensuring

that the appropriate documents are maintained in the eRoom. All information submitted will be retained according to GRC procedures, per requirements NPD 1440.6 and NPD 1441.1.

5. Resource Requirements

5.1 Funding Requirements

Funding for the task is approved annually during the Program Planning Budget and Execution (PPBE) and progress against the spending plan is reviewed during the Human Research Program's quarterly reviews.

Table 5.1 Funding requirements by fiscal year

Fiscal Year						
FTE						
FTE Cost						
Purchases						
Total Cost						

5.2 Facility Requirements

The laboratory work included in the Work Breakdown Structure (WBS) will be conducted in the laboratories at the NASA Glenn Research Center.

6. Schedule

This is the schedule for this project.

The technical milestones are defined as follows:

7. Work Breakdown Structure (WBS)

This section is the Work Breakdown Structure (WBS) for this project.

1. Define the scope and objective of the Fluid Resuscitation project
   1.1. Determine the conditions that require IV fluids
   1.2. Define the type(s) of IV fluid to be included in this study
   1.3. Define the deliverables – algorithm or hardware
2. Develop a technical approach
   2.1. Define the problem statement
   2.2. Perform literature/tech-watch search
      2.2.1. Determine any existing decision criteria/concepts
      2.2.2. Determine any existing hardware
      2.2.3. Determine any candidate technologies
   2.3. Perform trade studies and report results
   2.4. Develop the operational concept for the Algorithm-based Fluid Resuscitation system
      2.4.1. Develop the decision criteria to control the delivery of IV fluid
      2.4.2. Develop the feedback loops
   2.5. Develop prototype hardware (?)
      2.5.1. Determine the hardware to monitor vitals
      2.5.2. Determine the IV fluid delivery mechanism
3. Determine resources
   3.1. Human resources – identify key personnel
   3.2. Material resources
4. Determine funding resources
5. Define management approach
   5.1. Determine task priority
   5.2. Develop tools for problem reporting and controls
   5.3. Develop records management and documentation management
6. Define a project schedule
7. Define the risks
8. Define a performance plan
   8.1. Define success criteria
   8.2. Define deliverables
9. Determine a strategy for technology transition

8. Strategy for Technology Transition

The deliverable is a TRL 6 system that provides autonomous, algorithm-based fluid resuscitation.

Feasibility and readiness for each subsystem will be evaluated throughout the technology development effort, keeping in mind the requirements for an algorithm-based fluid resuscitation system.

This task does not envision any restrictions on technology distribution, other than those imposed by the federal government's International Traffic in Arms Regulation (ITAR).

All significant interim reports and the final report will be provided to ExMC and will be archived on NASA servers designated by ExMC for that purpose.

9. Risk Management

The task shall follow the requirements of NPR 8000.4A, Agency Risk Management Procedural Requirements and GLPR 7120.5.30, Space Assurance Requirements. Accordingly, the task shall implement Continuous Risk Management (CRM) to ensure that risks are identified in a timely fashion and appropriate action taken. The task will use GRC's Risk Management Implementation Tool (RMIT), which allows the task to open, score, assign, develop actions, and track all task risks. The tool also provides graphical output to identify top task risks and view their mitigation as a function of time.

This task will update task risks in a manner to provide timely input to the HRP quarterly review.

10. Task Evaluation and Optional Key Decision Points (KDPs)

This section discusses task evaluation and optional key decision points for this project.

10.1 Key Decision Points

TDP review complete (TBD)

10.2 Task Evaluation

The target for closure of this task includes the delivery of a TRL 6 system for algorithm-based fluid resuscitation.

11. Security Plan

This is the security plan for this project.

12. Key Personnel and Bibliography

While the NASA-mandated matrix organization may cause individuals to change, competencies required to support the task will be maintained. Those key competencies include TBD.

This section introduces key personnel for this project and includes bibliographies.

12.1 Key Personnel

This section lists the key personnel on this project.

12.2 Bibliography

This section lists the references applicable to this project.

ExMC 4.12 http://humanresearchroadmap.nasa.gov/gaps/?i=436

13. Acronyms

ExMC	Exploration Medical Capabilities
FTE	Full Time Equivalent
GRC	Glenn Research Center
ISS	International Space Station
ITAR	International Traffic in Arms Regulation
KDP	Key Decision Point
PPBE	Planning, Programming, Budgeting, and Execution
TDP	Technology Development Plan
TRL	Technology Readiness Level
WBS	Work Breakdown Structure

14. References

Human Research Roadmap, http://humanresearchroadmap.nasa.gov/gaps/gap.aspx?i=436

Appendix A

Appendix B

Appendix C

Appendix D

Appendix E

Appendix F